K111942

TSRH® Spinal System
510(k) Summary

August 4, 2011

AUG 30 2011

I. **Company:**

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Lila Joe
Prin. Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name:** TSRH® Spinal System

III. **Classification Name(s):** Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, and Pedicle Screw Spinal System (per 21CFR Section 888.3050, 888.3060, and/or 888.3070, respectively);
Product Code(s): KWQ, KWP, MNI, MNH, NKB, OSH

IV. **Description:**

The TSRH® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, staples, plates, and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

A subset of TSRH® Spinal System components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® Plates, plates, and connecting components as well as CD HORIZON® Spinal System components cleared for pediatric use such as Low Profile MULTI-SPAN® CROSSLINK® Plates, and CD HORIZON® rods, screws, set screws and locking screws. Similarly to the TSRH® implants used in adult case, these components can be rigidly locked into a variety of configurations, with each construct being tailored-made for the individual case. All screws used in pediatric cases are only cleared for use via a posterior approach. All of the components used in pediatric cases are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy and medical grade cobalt –chromium-molybdenum alloy.

TSRH® Spinal System staples, unit rods, s-rods and 7.0 mm diameter rods are specifically excluded for use in pediatric patients.

Certain implant components from other Medtronic spinal systems can be used with the TSRH® Spinal System in non-pediatric components. These components include GDLH® rods, rod/bolt connectors, Variable Angle T-bolts, set screws and locking screws; DYNALOK® PLUS bolts, and VANTAGE™ Anterior Fixation System screws.

The hooks are intended for posterior use only. The staples are for anterior use only. The TSRH-3D® and TSRH® 3Dx™ connectors, and TSRH-3D® and TSRH® 3Dx™ screws are intended for posterior use only. Within the TSRH® family, the cobalt chromium rods should only be used with TSRH® 3Dx™ Spinal System. All CROSSLINK® Plates are for posterior use and the CROSSLINK® Axial and Offset Plates may be used anteriorly as well.

The TSRH® Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium or titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy. Medical grade titanium, titanium alloy, and/or cobalt-chromium-molybdenum alloy may be used together. Certain TSRH® Spinal System components may be coated with hydroxyapatite. Never use titanium, titanium alloy, and/or cobalt-chromium-molybdenum alloy with stainless steel in the same construct.

No warranties, express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog for further information about warranties and limitations of liability.

To achieve best results, do not use any of the TSRH® Spinal System implant components with components from any other system, except those components listed above, or any other manufacturer. As with all orthopaedic and neurosurgical implants, none of the TSRH® Spinal System components should ever be reused under any circumstances.

V. Indications for Use:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients using allograft and/or autograft, the TSRH® Spinal System is indicated as an adjunct to fusion for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the TSRH® Spinal System is indicated as an adjunct to fusion for skeletally mature patients using allograft and/or autograft: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint: (2) who are receiving fusions using autogenous bone graft only: (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spondylolisthesis, (3) fracture, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) pseudarthrosis, (7) tumor resection, and/or (8) unsuccessful previous attempts at spinal fusion.

When used as a unilateral supplemental fixation device in the antero-lateral thoracic/lumbar region, the TSRH® L-Plate and VANTAGE™ screws are intended for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

For anterior use only the TSRH® Spinal System has the additional indication of: spondylolysis.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the TSRH® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The TSRH® Pediatric Spinal System is intended to be used with allograft and/or autograft. Pediatric pedicle screw fixation is limited to a posterior approach.

VI. Summary of the Technological Characteristics

The purpose of this Special 510(k) submission is to include a 5.5mm diameter rod that is 500mm long and manufactured from ASTM F1537 Wrought Cobalt-28Chromium-6Molybdenum Alloy that is single annealed.

The legally marketed predicate is the CD HORIZON® Chromaloy 5.5mm diameter x 500mm long rod cleared to be used with the TSRH® Spinal System by the Agency in the K093058 (S.E. 10/28/2009) and the TSRH® Chromaloy+ Precut Contoured 5.5mm Diameter Rods in lengths from 30mm – 120mm cleared in K103049 (S.E. 12/23/2010).

The table below lists the differences between the predicate devices and the subject device.

Predicate CD HORIZON Spinal System (K093058)	Predicate TSRH® Spinal System (K103049)	Subject TSRH® Spinal System Rod
Material Wrought Cobalt - 28Chromium - 6Molybdenum, Double Annealed (ASTM F1537)	Wrought Cobalt - 28Chromium - 6Molybdenum, Single Annealed (ASTM F1537)	Wrought Cobalt - 28Chromium - 6Molybdenum, Single Annealed (ASTM F1537)
Length 500mm	30mm - 120mm	500mm
Diameter 5.5mm	Identical	Identical
Shape Straight	Contoured	Straight
Fundamental Scientific Technology (Rod and Screw System)	Identical	Identical

VII. Identification of Legally Marketed Devices

Documentation was provided demonstrating that the TSRH® Spinal System is substantially equivalent to other commercially available fixation systems including the TSRH® Spinal System in K093058 (S.E. 10/28/2009), K103049 (S.E. 12/23/2010), and K110070 (S.E. 6/8/2011).

VIII. Discussion of the Non-Clinical Testing

Subject Device: TSRH® 3Dx Chromaloy Plus Straight 5.5mm Diameter Rod

The test performed per ASTM F1798-97 (2008). "Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants." (approved 2003) was axial grip around the rod.

The test performed per ASTM F2193 (2002). "Standard Specifications and Test Methods fro Components Used in the Surgical Fixation of the Spinal Skeletal System." (approved June 2002) was four point fatigue testing.

Medtronic believes that the results of the testing performed above and supporting documentation provided in this Special 510(k) submission demonstrate that the subject TSRH® 3Dx Chromaloy Plus 5.5mm diameter x 500mm long rod does not introduce new issues of safety, effectiveness, or performance.

IX. Conclusion

The TSRH® 3Dx CHROMALOY™ + Straight 5.5mm Diameter Rod is identical to its predicate devices in the indications, material, diameter, sterilization, surgical technique, and fundamental scientific technology. Additionally, a risk analysis was completed and non-clinical mechanical testing was performed in accordance to ASTM F1798-97 and ASTM F2193 that demonstrates the subject device does not introduce new issues of safety, effectiveness, or performance. Therefore, the subject device is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2013

Medtronic Sofamor Danek USA, Inc.
% Ms. Lila Joe
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K111942
Trade/Device Name: TSRH Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: August 04, 2011
Received: August 05, 2011

Dear Ms. Joe:

This letter corrects our substantially equivalent letter of August 30, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K111942

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Prescription Use __X__ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices